UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,125	04/29/2002	Norman Bitterlich	F-7241	5539

28107 7590 10/14/2005

JORDAN AND HAMBURG LLP
122 EAST 42ND STREET
SUITE 4000
NEW YORK, NY 10168

EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,125	BITTERLICH, NORMAN	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 Februrary, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

500

DETAILED ACTION

Applicant's arguments, filed 2/22/2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Matter

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been added to claim 1 via the amendment to part e), which has changed the definition of the values of similarity dimensions to no longer being a value between the data being investigated and all available reference values. The value now set forth in said part e) is between the data being investigated, all available reference values, and the time in months. This changed definition for this part e) practice has not been found as filed, nor pointed to by applicant, and is therefore NEW MATTER. Claims, which depend from claim 1, also contain this NEW MATTER due to their dependence.

Another NEW MATTER limitation has been added to claim 1 via the amendment to part f) directed to changing the equation used for calculating the value for greatest similarity. It is noted that part f) previously indicated an equation for calculating the value of greatest similarity, but not by finding the maximum in a range of values of A_j,

but by finding the minimum value in the range of values of A_j. This changed definition for said part f) practice has not been found as filed and is therefore NEW MATTER. Claims, which depend from claim 1, also contain this NEW MATTER due to their dependence.

Specification

The amendment filed 7/05/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: A new equation for calculating the greatest similarity has been introduced not previously disclosed in the specification. It is noted that the amended specification paragraph f), page 5, previously indicated an equation for calculating the value of greatest similarity, but not by finding the maximum in a range of values of A_j, but by finding the minimum value in the range of values of A_j.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The modification, necessitated by amendment, in claim 1, line 11 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. Claim 1, line 11, "measuring, at one or more points in time" does not clearly disclose a function of time measuring practice, which is critical or essential to the practice of the invention. What is not included in the claim(s) that is, is not enabled by the disclosure. Osteodensitometry, which relates to this invention, requires, page 1, first paragraph, line 9, "measured values at least at three different times," which is not indicated in the claims. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The quantity of experimentation necessary is an important factor for enabling one skilled in the art to perform the experiment. Is one time point enough quantitative data to base a

conclusion on or does the analysis require at least three different time points for measuring values? If there are multiple time points, what is the appropriate interval between the time points? This invention relates to Osteodensitometry, which requires, p.1, paragraph 1, line 12, "significantly large intervals between the times of measuring?" In the specification page 2, second paragraph, line three, measured values "of real or mathematically simulated bone density loss" are electronically stored as a function of time. What are the acceptable, number of times and interval of times between, measured values? Additionally, the nature of this invention, being multiple complex mathematical steps, requires full disclosure of parameter values and influences on those values in order to enable predictability for the experimentation. Claims, which depend from claim 1, also fail to comply with the enablement requirement, due to their dependence from claim 1.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the formulation in the claims, claim 1, part a), lines 4-5, the modified parameter definition, necessitated by amendment, of "K", "K being the number of bone markers", remains vague and indefinite by not clearly defining the meaning or value of "K." For

example, does "K" refer to the bone markers in a population of patients or the bone markers for a single patient? Does "K" refer to the total number of bone markers or only to the number of different bone markers? Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also contain this uncertainty due to their dependence from claim 1.

The modification, necessitated by amendment, in claim 1, line 11 does not clearly define a relation between the measured values "at one or more points in time" and the practice of said times used in the processing of these values defined in formulae in parts a) – e) as required in 35 U.S.C. 112 second paragraph, which requires clear and concise claim wording as to the practice of a claimed invention. It may be assumed that claim 1, line 11, "measuring, at one or more points in time" corresponds to the time values in the formulae of the processing parts a) – e), but such an assumption conflicts with the requirements of 35 U.S.C. 112 second paragraph. Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also contain this lack of clarity due to their dependence from claim 1.

In claim 1, part b), line 2, the modification, a table of "measured" values, necessitated by amendment, does not previously set forth a meaning for such a table and continues to lack clear antecedent basis as to what is meant regarding such a table. Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also lack this clarity due to their dependence from claim 1.

In claim 1, part c), lines 4-5, the modification, "wherein W_1, W_2,...W_k, are weighting factors and, in a standard determination, W_k = 1," necessitated by

amendment, clearly states the role of W_k as a weighting factor. However, there remains a lack of definition for a set of values and what determines/ influences this set of values for W_k, which causes the claim to remain vague and indefinite. For example, although a standard determination for $W_k = 1$ is set forth in the claim, what is an acceptable range of values for W_k and what determines or influences this range of values is not set forth in the claim? Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also lack this clarity due to their dependence from claim 1.

In claim 1, part g), lines 4-5, the modification, "wherein $R_j(t)$ are reference functions for describing the anticipated course of the bone density loss for the type I," necessitated by amendment, sets forth that $R_j(t)$ are reference functions, but does not define a set of values for, or what influences, said reference functions. A review of the specification has not revealed a definition of what is meant by said reference functions. Therefore a lack of definition of what determines the values of $R_j(t)$ causes the claim to be vague and indefinite. Evaluation of these values is required in order to calculate the $R_j(t)$ values. Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also lack clarity due to their dependence from claim 1.

In claim 1, part f), line 1, "the first and second similarity dimensions" lacks clear antecedent basis as to what is meant regarding said first and second similarity dimensions, which has not been previously set forth in the claim because the modification, necessitated by amendment, to claim 1, part e). It may be assumed that the first and second calculations, for calculating the value of similarity dimensions, of the equation in part e), correspond to said first and second similarity dimensions, but such

an assumption conflicts with the requirements of 35 U.S.C. 112 second paragraph, which requires clear and concise claim wording as to the practice of a claimed invention. Clarification via clearer claim wording is requested. Claims, which depend from claim 1, also lack this clarity due to their dependence from claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel can be reached via telephone 1-571-272-0718.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is 1.571.273.8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is 1.571.272.0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 10/7/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER